Citation:

de Rougemont A, Normand S, Nazare JA, Skilton MR, Sothier M, Vinoy S, Laville M. Beneficial effects of a 5-week low-glycaemic index regimen on weight control and cardiovascular risk factors in overweight non-diabetic subjects. *Br J Nutr.* 2007 Dec; 98(6): 1,288-1,298.

PubMed ID: 17617942

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To assess the metabolic effects of low glycemic index and high glycemic index nutritional interventions on body composition and blood parameters in overweight, non-diabetic subjects.

Inclusion Criteria:

- Men and women aged 20 to 60 years
- Body mass index (BMI) 25 to 30kg/m^2
- Stable body weight over the previous three months
- Non-pathological results for pre-inclusion biological tests
- Report of sedentary or moderate physical activity
- Usual breakfast habit including cereals and representing 10% to 25% of the daily energy intake.

Exclusion Criteria:

- Pregnancy or women likely to become pregnant
- Post-menopausal women
- Any physiological or psychological illness that could influence the results
- Subjects likely to take medical drugs interfering with the biological parameters of the study
- Any metabolic disorders (including diabetes, dyslipidemia and glucose intolerance)
- Intense physical activity
- Blood donation within the past three months
- Report or evidence of excessive alcohol intake
- Eating disorders.

Description of Study Protocol:

Recruitment

80 potential subjects responded by telephone to the recruitment campaign, 68 were given further information about the study and underwent pre-inclusion tests, 40 were enrolled in the study.

Design

Five-week randomized, parallel two-arm trial of low- and high-glycemic dietary interventions.

Dietary Intake/Dietary Assessment Methodology

Subjects were instructed to evaluate and record the amount of food and beverages eaten each day using a five-day food diary.

Intervention

- The five-week intervention consisted of ad libitum diets in which the starches were replaced by either low- or high-glycemic index starchy foods. The subjects received individual guidance by a trained clinical dietitian during the pre-inclusion period, on day one and at the end of week three (day 21). Part of the starches was provided for both groups throughout the study. Subjects were asked to consume the same amount of starch as usual and change only the type of starch. They were also asked not to modify their dietary habits regarding the food patterns and the amount of fruit and vegetables eaten
- Low-glycemic index diet included foods with glycemic index lower than 50 (relative to glucose)
- High-glycemic index diet included foods with glycemic index higher than 70.

Statistical Analysis

- Differences between groups at baseline was calculated using the Mann-Whitney test
- Differences between groups in weight and cholesterol were assessed using analysis of covariance with baseline as a covariate
- Mean glycemic index and macronutrient distribution from dietary records at pre-inclusion, week three and week five were calculated on the basis of the amounts of food eaten and assessed by analysis of variance for repeated measures, testing for overall difference in level between diet groups (main effect of diet), change over time (main effect of time) and difference in time course between groups (diet x time interaction)
- Differences between groups on day one and 36, changes in fasting blood samples, insulin resistance and sensitivity indexes and substrate oxidation values were analyzed using analysis of covariance with baseline as a covariate.

Data Collection Summary:

Timing of Measurements

Five-day diet diaries were completed during the pre-inclusion period (day 11 to day 7), and in weeks three (day 16 to day 20) and five (day 31 to day 35).

Dependent Variables

Body weight, fat mass, waist to hip ratio, blood glucose, insulin, c-peptide, total cholesterol (TC), HDL- and LDL-cholesterol, triacylglycerol, non-esterified fatty acids, carbohydrate oxidation,

lipid oxidation.

Independent Variables

- High glycemic index diet
- Low glycemic index diet.

Control Variables

Baseline values.

Description of Actual Data Sample:

- *Initial N:* 40 (20 males and 20 females)
- *Attrition (final N):* 38 (20 males and 18 females)
- *Mean age:* (Standard error of the mean) 36.3 (2.0) years for the low-glycemic index group and 40.4 (2.2) years for the high-glycemic index group
- *Anthropometrics:* There were no significant (NS) differences between groups at baseline
- *Location:* France.

Summary of Results:

Changes in body weight, BMI, TC and LDL-cholesterol after five weeks of an ad libitum low-glycemic index or high-glycemic index diet. There were no differences in baseline values between groups.

Variables	Low Glycemic Index Diet Group (N=19) Mean Change (Standard Error of the Mean)	High-glycemic Index Diet Group (N=19) Mean Change (Standard Error of the Mean)	P-value for Difference in Changes Between Groups
Body weight (kg)	-1.1 (0.3)*	-0.2 (0.2)	0.04
BMI (kg/m^2)	-0.4 (0.1)**	-0.1 (0.1)	0.03
Body fat mass	-0.7 (0.6)	-0.2 (0.4)	0.50
Total cholesterol (mmol per L)	-0.52 (0.12)***	-0.24 (0.13)	>0.05
LDL-C	-0.36 (0.13)****	-0.22 (0.11)	>0.05

*P-value for difference between baseline and at five weeks = 0.004.

**P-value for difference between baseline and at five weeks = 0.005.

***P-value for difference between baseline and at five weeks = <0.001.

****P-value for difference between baseline and at five weeks = 0.01.

Key Findings

- Mean body weight decrease was significant in the LGI group and was significantly greater than in the HGI group
- After five weeks of intervention, fasting insulin and glucose did not change significantly in the low-glycemic index group while c-peptide concentrations showed a significant decrease ($P<0.05$). In the high-glycemic index group, fasting insulin and c-peptide concentrations did not change significantly, while glucose concentrations showed a small, but significant decrease ($P=0.002$). There were NS differences in changes between groups for these three variables.
- For blood lipids, there was a significant decrease in TC and LDL-C during the five weeks for the low-glycemic index group. No other significant differences were found within or between groups for any of the other lipid parameters
- There was no evidence of improvement of risk markers for type 2 diabetes
- In the low-glycemic index group, there was a trend toward increased satiety before lunch compared with the high-glycemic index group ($P=0.09$)
- After five weeks, all subjects in the low-glycemic index group reached the defined target of less than 50 for glycemic index, while the defined target for the high-glycemic index group (more than 70) was not reached. Energy intakes did not differ after five weeks.

Author Conclusion:

The five-week ad libitum low-glycemic index diet resulted in a decrease in body weight and an improvement in lipid profile (total and LDL-C).

Reviewer Comments:

- *Author comments: The study showed that lowering the glycemic index of daily meals with simple dietary recommendations is relatively simple to implement in the medium term and was well-accepted by all subjects despite the inevitable feeding strains*
- *Short-term study, small number of patients, only small changes in a few outcome parameters.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes

4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes

4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	N/A
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A

7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	???
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	???
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	No
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes